

Defendant Pennsylvania Attorney General Michelle Henry (“Defendant”), through counsel, hereby submits this Brief in Opposition to the Motion for a Preliminary Injunction filed by Leda Health Corporation and Madison Campbell (“Plaintiffs”). For reasons that follow, Defendant respectfully requests that the Plaintiffs’ Motion for Preliminary Injunction be denied.

Plaintiffs initiated this counseled civil rights action by filing a Complaint in the United States District Court for the Western District of Pennsylvania on June 17, 2024. See Complaint [ECF 1]. In the Complaint, Plaintiffs allege violations of their First Amendment right to protected speech. Id. at 18–20. These allegations were made in response to the issuance of a cease-and-desist letter to Plaintiffs, where the Pennsylvania Office of Attorney General (“OAG”), through the Health Care Section (“HCS”), threatened legal action for Plaintiffs’ failure to comply with Pennsylvania’s consumer protection laws.

In addition to filing a Complaint, Plaintiffs submitted a Motion for a Preliminary Injunction and Memorandum in Support [ECF 2] on June 17, 2024.

Subsequently, on June 18, 2024, HCS filed a lawsuit against Leda Health and Madison Campbell in the Court of Common Pleas for Allegheny County, Pennsylvania. The lawsuit alleges that Leda Health and Madison Campbell are engaging in unfair and deceptive business practices in violation of Pennsylvania's Unfair Trade Practices and Consumer Protection Law ("UTPCPL," "Consumer Protection Law," or "CPL"), 73 Pa. C.S.A. § 201 *et seq.*

Following entries of appearance for Defendants Pennsylvania Attorney General Michelle Henry and New York Attorney General Letitia James, the Court issued a scheduling order [ECF 24] pertaining to the Motion for Preliminary Injunction. A response to the Plaintiffs' Motion is due on or before July 31, 2024. Id.

II. DEFENDANT'S COUNTER-STATEMENT OF FACTS

Plaintiff Leda Health Corporation ("Leda Health") is a for-profit business corporation and has a business address at 3803 Butler Street, Pittsburgh, Allegheny County, Pennsylvania 15201. Plaintiff Madison Campbell is an adult individual and the Chief Executive Officer ("CEO") of Leda Health.

Leda Health was formerly known as "Me Too Kits." Through its website, www.leda.co, and its *YouTube* channel, Leda Health advertises, markets, and sells products and services to hospitals, organizations, legislators, and universities for eventual use by individual members of these organizations. Leda Health's primary product is a DNA collection kit, what it calls the Early Evidence Kit ("EEK"). Leda Health markets EEKs as self-administered tests for sexual assault survivors for eventual use in judicial proceedings.

The EEK contains four sets of diagnostic swabs and sterile water for self-administered collection of DNA evidence, instructions for administration, an intake form for documenting the collection, two plastic bags with unique barcodes for storing items, tamper-evident tape, and a

prepaid FedEx shipping bag. See Complaint [ECF 1], at ¶22. Leda Health avers that the company developed EEKs “to enable survivors of sexual assault to self-collect and store evidence, including DNA, when a traditional sexual assault forensic exam is not possible or against the survivor’s wishes.” Id. at ¶1. Plaintiffs claim that “Leda Health’s Care Team guides survivors through the EEK’s step-by-step process for DNA self-collection and documentation.” See Pls.’ Mot. for Prelim. Inj. [ECF 2], at 12.

Despite this, Plaintiff’s website contains a disclaimer indicating it is not a medical care provider and is not a replacement for professional medical care. See NYAG Assurance of Discontinuance [ECF 1-5], at 11. Leda Health further disclaims that it “cannot guarantee that any information collected through [its] Early Evidence Collection Kit will be offered, admitted, or relied upon in a court of law. The ultimate admissibility and reliability of information that you collect through Leda Health’s services will be dependent on the specific circumstances of your case and applicable law.” See Exhibit I (Terms and Conditions), at 2. “To maximize the accuracy and reliability of information collected through our services, you must closely adhere to and follow the instructions accompanying or kit, application, and services.” Id. at 13.

Plaintiffs make clear that the target of these kits is survivors of sexual assault. See Complaint [ECF 1], at ¶2 (“Leda Health meets survivors where they are and affords them options. EEKs allow survivors who do not want a traditional ‘rape kit’ test to gather critical evidence in a safe, private, and effective way.”) Targeting this specific population differentiates Leda Health from a DNA testing lab—rather than simply providing a DNA test, Plaintiffs represent that their product will be of use to a factfinder in a future criminal or civil proceeding. See Pls.’ Mot. for Prelim. Inj. [ECF 2], at 11 (“[A]s long as a chain of custody can be established

with sufficient completeness, neither Pennsylvania nor New York law generally prohibit the introduction of self-collected evidence in court proceedings.”).

Leda Health’s representation to consumers via its website and statements by its CEO drew the attention of HCS, whose role is to protect the public from unfair health care practices by investigating and taking legal action on behalf of consumers against health care organizations it deems to be in violation of Pennsylvania law.

To that end, HCS sent Leda Health a Cease-and-Desist Notification on May 24, 2024. See Cease-and-Desist Notification [ECF 1-3]. In it, HCS warned Plaintiffs to “immediately cease and desist advertising, marketing, and sales of products and services relating to its ‘Early Evidence Kits,’ to consumers on the basis that Leda Health’s business practices related to [EEKs] violate the [Consumer Protection Law].” Id. at 1. The letter addressed advertising HCS deemed to violate consumer protection laws, including Leda Health’s conflation of their product with kits regulated by the Pennsylvania Department of Health and their failure to inform consumers that approved kits are available to sexual assault survivors at no charge. Id. at 2. In response, Leda Health filed a federal lawsuit, including a preliminary injunction motion. In the Motion, Plaintiffs request that the Court declare HCS’s law enforcement “actions unconstitutional” and prohibit HCS from “coercing Plaintiffs’ protected speech.” See Pls.’ Mot. for Prelim. Injun. [ECF 2] at 38–39.

III. ENFORCEMENT OF PENNSYLVANIA’S CONSUMER PROTECTION LAW

The Pennsylvania Office of Attorney General, through the Health Care Section, is empowered to enforce the Consumer Protection Law’s prohibition of unfair or deceptive acts or practices. The General Assembly and the Pennsylvania Supreme Court gift the Office a wide-berth in the consumer protection space.

In sweeping fashion, the CPL prohibits “unfair or deceptive acts or practices” and then proceeds to list twenty-one instances of such conduct, concluding with what is commonly called the “catch-all” set forth at 73 P.S. § 201-2(4)(xxi). Com. v. Bell Telephone Co., 551 A.2d 602, 604 (Pa. Cmwlth. 1988). The Pennsylvania Supreme Court has unequivocally held that the CPL is to be construed liberally to effect its objective of preventing unfair or deceptive practices and protecting the public. Com. v. Monumental Properties, 329 A.2d 812, 816 (Pa. 1974) (holding that as a statute designed for the prevention of fraud, the CPL must be liberally construed to effect its purpose). The sweeping language of the CPL makes plain the legislative intent that unfairness and deception in all consumer transactions must be halted. Id. at 817. See also In re Fricker, 113 B.R. 856, 872–73 (Bankr. E.D. Pa. 1990).

An act or practice is deceptive or unfair if it has the capacity or tendency to deceive. Com. v. Peoples Benefit Servs., Inc., 923 A.2d 1230, 1236 (Pa. Cwlth. 2007). Actual injury is not required as deception itself is the evil designed to be prevented. Com. v. Nickel, 26 Pa. D.&C.3d 115, 120 (Pa. Com. Pl. Mercer 1983). Neither the intention to deceive nor actual deception must be proved; rather, it need only be shown that the acts and practices are capable of being interpreted in a misleading way. Id. The application of the CPL does not turn on the intent of the actor; rather, the focus is on the likely impression of the consumer arising from the totality of what is said and implied in the advertisement or solicitation. See Peoples Benefit Servs., Inc., 923 A.2d at 1236; Com. v. Hush-Tone Industries, Inc., 4 Pa. Cmwlth. 1, 22 (1971).

In addition to preventing misleading advertising, the CPL was designed to promote full disclosure of information to consumers and to equalize market position and strength between buyer and seller. Gabriel v. O’Hara, 534 A.2d 488, 491 n.6 (Pa. Super. 1987). The CPL contemplates that in appropriate circumstances a court may require affirmative disclosures by a

seller to prevent misrepresentation and deception. Monumental Properties, 329 A.2d at 829. See also Zwiercan v. Gen. Motors Corp. et al, 58 Pa. D.&C.4th 251 (Pa. Com. Pl. Phila. 2002).

The Pennsylvania Office of Attorney General has a critical role in ensuring the consumer protection laws are followed. The Office's role in this regard is beyond dispute. The Attorney General is the chief law enforcement officer for the Commonwealth as a whole and "shall exercise such powers and perform such duties as may be imposed by law." Pa. Const. art. IV, § 4.1. Section 204(c) of the Commonwealth Attorneys Act provides that "the Attorney General shall represent the Commonwealth and all Commonwealth agencies . . . in any action brought by or against the Commonwealth or its agencies." 71 P.S. § 732-204(c). The Attorney General is elected statewide and is accountable to the broader electorate. The office represents the public interests of the entire Commonwealth. Com. by & through Krasner v. Att'y Gen., 309 A.3d 265, 277 (Pa. Cmwlth. 2024). The Attorney General, as a statewide elected official, is the "final voice" for the Commonwealth. Com. by & through Krasner v. Att'y Gen., 309 A.3d 265, 271 (Pa. Cmwlth. 2024).

The UTPCPL authorizes the Attorney General to bring an action in the name of the Commonwealth of Pennsylvania, to restrain by temporary or permanent injunction, unfair or deceptive acts or practices in the conduct of any trade or commerce declared unlawful by Section 201-3 of the Consumer Protection Law. 73 P.S. § 201-4.

[T]he Attorney General is imbued with the express authority to file suit against "any person," whenever the Attorney General determines that such a person "is using or is about to use any method, act or practice declared by [73 P.S. § 201-3] to be unlawful, and that proceedings would be in the public interest[.]" 73 P.S. § 201-4. Section 2(2) of the Law defines "person" as "natural persons, corporations, trusts, partnerships, incorporated or unincorporated associations, and any other legal entities." Id. at § 201-2(2).

Anadarko Petroleum Corp. v. Com., 206 A.3d 51, 59 (Pa. Cmwlth. 2019). The Attorney General’s belief that a violation has occurred is sufficient to file suit. That “belief may be subject to challenge and ultimately may be proven to be unfounded,” but in commencing a lawsuit, it is sufficient that the Commonwealth believes that a violation of law occurred to set forth a cause of action against a company. Com. by Zimmerman v. Nat’l Apartment Leasing Co., 519 A.3d 1050, 1054 (Pa. Cmwlth. 1986).

Plaintiffs’ Motion is an attempt to circumvent Pennsylvania law through misuse of the federal courts.

IV. ARGUMENT

Preliminary injunctions are an “extraordinary and drastic remedy.” Mazurek v. Armstrong, 520 U.S. 968, 972 (1997). A preliminary injunction is not a “shortcut to the merits”; rather, it is “designed to protect the court’s ability to see the case through.” Del. State Sportsmen’s Ass’n, Inc. v. Del. Dep’t of Homeland Sec., 2024 WL 3406290, at *9 (3d Cir. 2024). Plaintiffs’ Motion falls exceedingly short of justifying such a drastic remedy.

A party seeking a preliminary injunction must show: (1) a likelihood of success on the merits; (2) that it will suffer irreparable harm if the injunction is denied; (3) that granting preliminary relief will not result in even greater harm to nonmoving parties; and (4) that the public interest favors such relief. Arrowpoint Cap. Corp. v. Arrowpoint Asset Mgmt., LLC, 793 F.3d 313, 318–19 (3d Cir. 2015).

The injunction should be issued only if the plaintiff produces enough evidence to sufficiently convince the court that all four factors favor preliminary relief. Opticians Ass’n v. Indep. Opticians, 920 F.2d 187, 192 (3d Cir. 1990). The “failure to establish any element [of that test] renders a preliminary injunction inappropriate.” NutraSweet Co. v. Vit-Mar Enters. Inc.,

176 F.3d 151, 153 (3d Cir. 1999). Preliminary injunctions should issue only in a “clear and plain case.” Bramble v. Wetzel, 2021 WL 3190710, at *2 (M.D. Pa. 2021). In considering an application for a preliminary injunction, “to doubt is to deny.” Madison Square Garden Corp. v. Braddock, 90 F.2d 924, 927 (3d Cir. 1937).

A. The relief requested is an improper use of a preliminary injunction.

As a preliminary matter, even if Leda Health’s underlying constitutional claims could overcome the multiple defects described below, its request for injunctive relief does not comport with the specificity requirements of Federal Rule of Civil Procedure 65(d). The Rule provides that a request for an injunction must state its terms specifically and describe in reasonable detail the act or acts restrained or required. Fed. R. Civ. P. 65(d)(1)(B)–(C).

The relief requested suffers from a fundamental defect: it is unclear how an injunction against the Pennsylvania Office of Attorney General would function. Leda Health asks the Court to “enter a preliminary injunction declaring the Defendants’ actions unconstitutional and prohibiting Defendants from coercing Plaintiffs’ protected speech.” [ECF 2] at 38–39. Plaintiffs’ requested relief is couched in broad, non-specific terms. The injunction asks the Court to declare Leda Health beyond the reach of Pennsylvania’s consumer protection laws. Such a holding would significantly hinder the Office’s ability to enforce the CPL and protect the public.

Plaintiffs’ request runs counter to the purpose of a preliminary injunction. An injunction is a scalpel, not a sword. Rule 65(d)’s basic specificity requirement reflects the acknowledgment that “[t]he party constrained is entitled to ‘fair and precisely drawn notice of what the injunction actually prohibits’ because serious consequences may befall those who do not comply with court orders.” Louis W. Epstein Family P’ship v. Kmart Corp., 13 F.3d 762, 771 (3d Cir. 1994) (*quoting* Granny Goose Foods v. Bhd. of Teamsters, Local No. 70, 415 U.S. 423, 444

(1974)). Broad, nonspecific language that merely enjoins a party to “obey the law” does not give the restrained party fair notice of what conduct will risk contempt. Id. at 771.

Far from seeking a clear, specific mandate, Leda Health seeks a broad, non-specific decree that Pennsylvania’s enforcement actions against Leda Health somehow violate the First Amendment and thus should be enjoined. Their proposed relief is tantamount to a request that the Pennsylvania Attorney General abdicate her statutorily defined role to enforce the consumer protection laws. Such a result would contravene spirit and intent of the UTPCPL, 73 P.S. § 201-4, and make it impossible for the Attorney General to understand precisely what conduct the injunction prohibits. Plaintiffs’ proposed relief, if granted, would seem to preclude even an investigation into their business practices—an absurd result.

Their failure to clearly articulate the relief they seek is fatal to their request. Plaintiffs have failed to demonstrate the basic criteria for issuance of an injunction, and should be denied.

B. Likelihood of Success on the Merits

In determining whether a preliminary injunction should issue, the Court should consider whether the party seeking the preliminary injunction is likely to succeed on the underlying legal claims. Key to this analysis is whether the case is properly before the Court. Defendants aver that the circumstances of this case require the Court to abstain under Younger v. Harris, 401 U.S. 37 (1971). The Pennsylvania Office of Attorney General, pursuant to the Consumer Protection Law, is authorized to engage in enforcement action in state court against companies engaging in unfair or deceptive acts or practices. 73 P.S. § 201-1, *et seq.* The federal courts cannot enjoin the Attorney General from lawfully pursuing through investigation or litigation in state court what the Attorney General, in her judgment, deems to be a violation of the consumer protection laws.

If the Court elects not to abstain, injunctive relief is still improper because Plaintiff's constitutional claims are not likely to succeed on the merits. Plaintiffs' underlying claims are (1) First Amendment retaliation; and (2) First Amendment coercion. Plaintiffs fail to show that they engaged in constitutionally protected conduct. Where, as here, a company is alleged to be engaging in unfair and deceptive practices in violation of the consumer protection law, the First Amendment provides no protection. Va. State Bd. of Pharmacy v. Va. Citizens Consumer Counsel, 425 U.S. 748, 771 (1976) ("Untruthful speech, commercial or otherwise, has never been protected for its own sake.").

Even if Plaintiffs could show that their conduct is within the realm of protected commercial speech, the Pennsylvania Attorney General has a substantial interest in ensuring that sexual assault survivors are not misled by Plaintiffs' claims. Plaintiffs' misleading claims may result in survivors' forgoing sexual assault forensic examinations that would assist them in seeking justice. HCS's enforcement actions are actions narrowly tailored to carry out the Commonwealth's substantial and legitimate governmental interest.

1. Abstention

As discussed above, the Pennsylvania Office of Attorney General is expressly authorized by statute to enforce the Consumer Protection Law in state court. 71 P.S. § 732-204(c); 73 P.S. § 201-4. The CPL is to be liberally construed. Com. v. Monumental Properties, 329 A.2d 812, 816 (Pa. 1974). Plaintiffs' insistence that this Court enjoin the Attorney General's consumer protection enforcement power implicates important considerations of equity and comity—specifically, Plaintiffs are requesting that the Court substitute its judgment of the application of Pennsylvania's Consumer Protection Laws for the judgment of the Attorney General and the

Pennsylvania state courts. This the Court should not do. Abstention under Younger v. Harris creates a barrier to the injunctive relief Plaintiffs seek. 401 U.S. 37 (1971).

Younger abstention is based on the view that federal courts should not interfere with state courts and that the availability of state court proceedings is sufficient to protect constitutional rights. State courts are to be trusted to adequately uphold civil rights, including those guaranteed by the First Amendment.¹ There is no civil right to have a federal claim, such as the First Amendment claim raised here, heard by a federal court unless exclusive jurisdiction over a federal cause of action has been vested in the federal courts. Battaglia v. Gen. Motors, 169 F.2d 254, 257 (2d Cir.), *cert. denied*, 335 U.S. 887 (1948); Carr v. Axelrod, 798 F. Supp. 168, 172 (S.D.N.Y. 1992), *aff'd*, 996 F.2d 302 (2d Cir. 1993).

HCS's enforcement does not involve federal causes of action; rather, the unfair business practices alleged and HCS's authority to regulate these practices through an investigation and civil lawsuit are creations of state—not federal—law. While Plaintiffs argue that HCS's cease-and-desist notification and subsequent lawsuit implicate constitutionally protected speech, this construction is raised by Plaintiffs as an affirmative defense, not by any cause of action in Allegheny County filing. The fact that Plaintiffs may raise a constitutional question in response to the HCS's Complaint is irrelevant to the analysis. Louisville & Nashville R. Co. v. Motley, 211 U.S. 149, 152 (1908) (holding that a “suggestion of one party, that the other will or may set up a claim under the Constitution or laws of the United States, does not make the suit one arising

¹ As initially developed, the Younger doctrine limited the power of the federal courts to interfere with pending state *criminal* proceedings. Subsequently, however, the United States Supreme Court applied Younger to civil cases in state court, particularly where, as here, the state government itself is a party to the civil litigation. *See, e.g., Huffman v. Pursue, Ltd.*, 420 U.S. 592, 604 (1972) (holding that the district court should have abstained under Younger as federal court injunctive and declaratory relief were “likely to be every bit as great as it would be were this a criminal proceeding”).

under that Constitution or those laws.”) Whether Plaintiff’s activities fall within the scope of the Consumer Protection Law is purely a question of state law. Id.

Further, the injunctive relief Plaintiffs seek would prevent state judges “from exercising state-authorized judicial powers vital to the administration of justice,” and would implicate “the federalism and comity strand of the *Younger* doctrine.” Johnson v. Kelly, 583 F.2d 1242, 1249 (3d Cir. 1978). If this Court were to enjoin the state proceedings in accordance with Plaintiffs’ request, state court judges would be prevented from adjudicating the legitimacy of the Attorney General’s claim that Plaintiffs are violating the consumer protection laws. Id. (citing Juidice v. Vail, 430 U.S. 327 (1977)). Nothing prevents Plaintiffs from asserting their federal rights in state court as affirmative defenses. See Carr, 798 F. Supp. at 173 (“[s]tate courts are bound to uphold the federal constitution. We are unwilling to assume that New York’s fine courts will not.”) (citing City of Greenwood v. Peacock, 384 U.S. 808, 827–28 (1966)). The Allegheny County Court may determine that Plaintiffs have not violated the Consumer Protection Law, negating the need to resolve the federal question at all.

Principles of comity and equity underlying *Younger* abstention instruct federal courts to exercise restraint from interference in state affairs unless necessary. Morales v. Turman, 562 F.2d 993, 996 (5th Cir. 1977). “State governments have wide discretion in dealing with their affairs.” Id. See also Rizzo v. Goode, 423 U.S. 362, 378–79 (1976) (holding that when a plaintiff seeks to enjoin the activity of a government agency, his case must contend with “the well-established rule that the Government has traditionally been granted the widest latitude in the ‘dispatch of its own internal affairs’”) (quoting Cafeteria and Restaurant Workers Union Local 473 A.F.L.-C.I.O. v. McElroy, 367 U.S. 886, 896 (1961)); Welsch v. Likins, 550 F.2d 1122, 1131 (“under our federal system of government the federal courts should be most reluctant to

interfere in local government affairs and should do so only where the case is clear and the need for federal interference urgent”). Plaintiff’s proposed injunctive relief creates an “indisputably sharp limitation” on the latitude afforded to the Pennsylvania Office of Attorney General in its responsibility to enforce Pennsylvania’s consumer protection laws. Rizzo, 423 U.S. at 379. On these principles, this Court must deny the preliminary injunction based on the high likelihood that abstention will foreclose Plaintiffs’ claims on the merits. See, e.g., Gibson v. Berryhill, 411 U.S. 564, 577 (1973) (noting that Younger abstention contemplates the outright dismissal of the federal suit, and the presentation of all claims, both state and federal, to the state courts).

2. Leda Health’s conduct does not fall within the scope of the First Amendment or, alternatively, may be regulated consistent with restrictions on commercial speech.

Plaintiffs allege that the Pennsylvania Office of Attorney General (1) retaliated against them for engaging in constitutionally protected activity; and (2) are silencing their marketing efforts, implicating protected speech. In their view, any attempt to bring them in compliance with Pennsylvania law is a First Amendment violation. They are wrong. Plaintiffs, through their unfair and deceptive business practices, are not engaging in protected speech. Misleading and deceptive commercial speech has long been deemed unprotected by the First Amendment. Because the First Amendment provides no refuge for their deceptive marketing, both counts listed in Plaintiffs’ Complaint fail. This Court should reject the Plaintiffs’ grandiose claim that a routine cease-and-desist letter by Pennsylvania’s chief law officer violates the First Amendment.

Even if not misleading, the state may restrict commercial speech, but its regulations of such speech are subject to intermediate scrutiny. Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm. of N.Y., 447 U.S. 557, 566 (1980). The Supreme Court has explained the standard:

In commercial speech cases, a four-part analysis has developed. At the outset, we must determine whether the expression is protected by the First Amendment. For commercial speech to come within

that provision, it at least must concern lawful activity and not be misleading. Next, we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than necessary to serve that interest.

Id.

a. Leda Health’s advertising is misleading and therefore unprotected by the First Amendment.

Plaintiffs’ advertising of EEKs enjoys no First Amendment protection because it is misleading² commercial speech. United States v. Bell, 414 F.3d 474, 478–79 (3d Cir. 2005). The threshold inquiry is whether the commercial speech is false or misleading. It is well-established that such speech can be prohibited without any First Amendment problem. See In re R.M.J., 455 U.S. 191, 203 (1982) (“Misleading advertising may be prohibited entirely.”). There can be no constitutional objection to the suppression of commercial messages that do not accurately inform the public about lawful activity. The government may ban forms of communication more likely to deceive the public than to inform it. Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of N.Y., 447 U.S. 557, 563–64 (1980).

Applying this test to Leda Health’s marketing, it is apparent that their advertising misrepresents EEKs as providing a net benefit to sexual assault survivors. They imply that proper use of their product “maximizes” the likelihood of admissibility. See Exhibit I (Terms and Conditions), at 2, 13. It is the overall impact of Plaintiffs’ advertising that makes it deceptive. See Beneficial Corp. v. FTC, 542 F.2d 611, 617 (3d Cir. 1976) (“tendency of advertising to deceive must be judged from viewing it as a whole”); Federal Trade Commission v. Sterling

² It bears repeating at this juncture that the proper forum for a factual determination of whether the speech at issue here is misleading is the Allegheny Court of Common Pleas. Further, at this early stage in the litigation, the Court is without a full record to determine whether and to what extent Plaintiffs’ marketing may be misleading.

Drug, 317 F.2d 669, 674 (2d Cir. 1963) (holding that the cardinal factor for determining the deceptiveness of advertising is the ultimate impression on the buying public). Plaintiffs advertise EEKs as an effective alternative to a sexual assault forensic examination. See Complaint [ECF 1] at ¶2 (“EEKs allow survivors who do not want a *traditional* ‘rape kit’ test to gather *critical* evidence in a safe, private, and *effective* way”) (emphasis added). Plaintiffs claim, without evidence, to provide “more (and different) resources than what the government provides,” citing specific deficiencies in “traditional rape kits” like “privacy concerns” and “distrust” of law enforcement. See Pls.’ Mot. for Prelim. Injun. [ECF 2] at 2. However, they fail to adequately inform consumers of the potential harms inherent in the self-collection of evidence in the context of a sexual assault. HCS alleges that Plaintiffs’ advertising gives sexual assault survivors the false impression that EEKs are a replacement for—or even an improvement on—an examination performed at a healthcare facility. Plaintiffs mislead survivors by giving them the impression that EEKs have the same forensic utility as a “traditional ‘rape kit.’”

This overall impression is a false one. Leda Health’s *YouTube* video describing their EEKs provides an example of the misleading nature of their advertising. In the video, Plaintiffs describe Leda Health as a group comprised of “survivors, *nurses*, advocates, and *lawyers*.” Including nurses and lawyers in their advertising gives the impression that Leda Health provides specific expertise in medical evidence collection and the presentation of that evidence in a court of law. Their kit includes “tamper evident” tape, giving the impression that an adequate chain-of-custody will be followed and maintained. They claim that their mobile app enables users to “timestamp the collection process.” The video states that survivors can capture photos and videos, and chat live with care team members, who are trained in virtual forensics collection, and are available to testify in court on behalf of users. See “Unboxing Leda’s Early Evidence Kit,”

Leda Health Channel, YouTube, https://www.youtube.com/channel/UC-BAgE38wU_ZfjHJlePRSnA.

As Plaintiff states in her Declaration, self-collection kits are “forensic devices, not medical ones.” [ECF 2-1] at ¶10. Their purported “forensic” use is inherent to their name: **Early Evidence Kits**. The product’s features go beyond a simple DNA test—their marketing implies support up to and throughout a criminal or civil proceeding. The implication is that their tests provide *credible* evidence that has a high likelihood of admissibility in a court proceeding. These claims are unproven and unprecedented. Despite Leda Health’s assurances that a user of their service will be supported by admissible forensic testimony, they cannot substantiate these claims. At best, their marketing could be described as aspirational. It is misleading, HCS alleges, because it creates the overall misleading impression that the evidence collected will be admissible in court. Plaintiffs’ disclaimer is “insufficient to contradict the overall message of [their] advertisement that the evidence will be admissible in court.” See NYAG Cease and Desist Notification [ECF 1-4] at 2–3.

Because Plaintiffs’ advertising and marketing are misleading, they are outside of the protection of the First Amendment. The analysis should end here, as the government may ban forms of communication more likely to deceive the public than to inform it. Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of N.Y., 447 U.S. 557, 563 (1980).

b. The Pennsylvania Office of Attorney General has a substantial interest in regulating Leda Health’s advertising of its services and products.

Even if the commercial speech is not misleading, the second prong of the analysis is whether there is a substantial government interest in regulating Plaintiffs’ marketing tactics. Commercial speech, or advertising, represents a category of speech that receives a reduced level of First Amendment protection. Commercial speech is “speech which does no more than propose

a commercial transaction,” Va. State Board of Pharmacy v. Va. Citizens Consumer Council, 425 U.S. 748, 762 (1976), or “speech related solely to the economic interests of the speaker and its audience.” Cent. Hudson Gas & Elec. v. Pub. Serv. Comm’n of N.Y., 447 U.S. 557, 561 (1980).

Where the facts present a close question, strong support that the speech should be characterized as commercial speech is found where the speech is an advertisement, the speech refers to a particular product, and the speaker has an economic motivation. Bolger v. Youngs Drugs Prods. Corp., 463 U.S. 60, 66–67 (1983). However, while the combination of all these characteristics provides strong support for the conclusion that regulated speech is properly characterized as commercial speech, each characteristic need not necessarily be present in order for speech to be commercial. Id. at 67 n.14.³

If the speech concerns lawful activity and is not misleading, the Court must determine “whether the asserted governmental interest is substantial.” Cent. Hudson, 447 U.S. at 566. If it is, the inquiry is “whether the regulation directly advances the governmental interest asserted,” and, finally, “whether it is not more extensive than is necessary to serve that interest.” Id. If each of these three inquiries are answered in the affirmative, the regulation is constitutional. Thompson v. Western States Medical Center, 535 U.S. 357, 367 (2002).

³ Plaintiffs’ Motion alleges that the speech at issue here is about “public issues,” occupying the “highest rung of the hierarchy of First Amendment values” and is entitled to “special protection.” [ECF 2] at 18 (*citing Connick v. Myers*, 461 U.S. 138, 145 (1983)). They are mistaken. Plaintiffs are engaged in speech for the purpose of selling a product—their EEKs. Linking their product to a “public question” aimed at bringing about “political and social change” is fundamentally flawed. Advertising which links a product to a current public debate is not thereby entitled to the constitutional protection afforded noncommercial speech. Bd. of Trustees of State Univ. of N.Y. v. Fox, 492 U.S. 469, 475 (1989). Coupling their product with discussions of deficiencies in the criminal justice system does no more to convert their commercial speech into political speech than “opening a sales presentation with a prayer or a Pledge of Allegiance would convert them into religious speech.” Id. at 474–75. Their communication is still commercial speech despite Plaintiffs’ attempt to entangle their product with issues of public concern. Id. at 475.

The Pennsylvania Office of Attorney General’s cease-and-desist notification, as well as its pending litigation in Allegheny County, directly advance substantial government interests. Specifically, Pennsylvania has a substantial government interest in the protection of consumers from misleading or confusing health-related marketing. See, e.g., Dwyer v. Cappell, 762 F.3d 275, 289 (3d Cir. 2014); Consumer Data Industry Ass’n v. Platkin, 2024 WL 1299256, at *25 (D.N.J. 2024) (finding a government interest in preventing consumer confusion and deception).

Beyond the general protection of consumers, Pennsylvania also has a substantial interest in ensuring the integrity of evidence collection in incidents of sexual assault. The Pennsylvania Department of Health provides minimum standards for providing sexual assault survivors with a medical examination and laboratory or diagnostic tests required to ensure the health, safety, and welfare of the victim. 28 Pa. Code § 117.52(a)(1). The standards are in place to facilitate the prosecution of persons accused of sexual assault. 35 P.S. § 10172.3(a). Pennsylvania’s existing statutory and regulatory scheme demonstrates the Commonwealth’s commitment to assuring that rape kits meet state-of-the-art minimum standards. 35 P.S. § 10172.3(a)(3).

The Pennsylvania Attorney General’s exercising her statutorily conferred enforcement power does not restrict more speech than is necessary to serve the governmental interest. See, e.g., Thompson v. Western States Medical Center, 535 U.S. 357, 367 (2002). Importantly, the United States Supreme Court has never interpreted this test as requiring “elimination of all less restrictive alternatives.” Bd. of Trustees of State Univ. of N.Y. v. Fox, 492 U.S. 469, 478 (1989). There must be a “fit” between the state’s desired ends and the means chosen to accomplish those ends. Id. at 480. The fit need not be perfect; rather, it must be reasonably in proportion to the interest served. Id. (*quoting In re R.M.J.*, 455 U.S. 191, 203 (1982)). Within those bounds governmental decision-makers may judge what manner of regulation may best be employed. Id.

The enforcement action complained of here is the cease-and-desist notification sent to Plaintiffs on May 24, 2024. The Commonwealth, pursuant to its authority under the CPL, issued the notification letter to Leda Health requesting that they cease all advertising, marketing, and sales of its products in the Commonwealth within seven (7) days. See HCS Cease and Desist [ECF 1-3] at 1. HCS informed Leda Health of its belief that Leda Health was violating the UTPCPL. Id. HCS further informed Leda Health that their products mislead Pennsylvanians by marketing and offering for sale EEKs which have not been found admissible in Pennsylvania courts are unlikely to be found to be admissible due to their insufficiency under the Pennsylvania Sexual Assault Kit requirements. Id. at 4. Finally, HCS advised Plaintiffs that failure to comply with the demand may result in further enforcement action, including injunctive relief, civil penalties, and other remedies provided for under Pennsylvania law. Id. at 6.

It is clear that the cease-and-desist letter is reasonably related to the Attorney General's duty to investigate and take legal action against entities it deems in violation of Pennsylvania's consumer protection laws. It is within the Attorney General's statutory authority to warn Leda Health of impending legal action. Further, the cease-and-desist letter, as well as the pending Allegheny County lawsuit, target only Leda Health's misleading speech. See, e.g., Com. by Preate v. Events Intern., Inc., 585 A.2d 1146, 1150 (Pa. Cmwlth. 1991) (holding that Attorney General's request for an order permanently enjoining defendants from engaging in deceptive business practices in the future was sufficiently tailored to satisfy the first amendment restrictions on prior restraints); Com. by Preate v. Watson & Hughey Co., 563 A.2d 1246, 1282 (holding that the injunctive relief which the Commonwealth, through the Attorney General, requested was narrowly tailored to achieve its goal of preventing fraud).

Finally, as to the state court litigation pending in Allegheny County, that court may, commensurate with the First Amendment as interpreted by the United States Supreme Court, enjoin Plaintiffs from engaging in fraudulent practices. Watson, 563 A.2d at 1282. Leda Health's constitutional rights are not violated by an injunction or other civil remedies precluding them from committing fraud and misrepresentation. Id.

Because enforcement actions of the Pennsylvania Office of Attorney General target only Plaintiffs speech claimed to be misleading, appropriate relief may be fashioned in state court without impinging on First Amendment concerns. Id. See also Bates v. State Bar of Ariz., 433 U.S. 350 (1977); Com. by Preate v. Pa. Chiefs of Police Ass'n, 572 A.2d 256, 258 (Pa. Cmwlth. 1990). Plaintiffs' request for a preliminary injunction should therefore be denied for failure to establish a likelihood of success on the merits.

C. Irreparable Harm

The second step in the analysis requires a showing that Plaintiffs will suffer irreparable harm if the injunction is denied. Plaintiffs fail to establish this element in their Motion [ECF 2].

Irreparable injury is established by showing that Plaintiff will suffer harm that “cannot be addressed by a legal or equitable remedy following trial.” Instant Air Freight Co. v. C.F. Air Freight, Inc., 882 F.2d 797, 801 (3d Cir. 1989). Plaintiff must show *immediate* irreparable injury, which is more than merely serious or substantial harm. ECRI v. McGraw-Hill, Inc., 809 F.2d 223, 226 (3d Cir. 1987). The word “irreparable” connotes “that which cannot be repaired, retrieved, put down again, atoned for[.]” Acierno v. New Castle Cnty., 40 F.3d 645, 653 (3d Cir. 1994). Additionally, the claimed injury cannot merely be possible, speculative, or remote. Dice v. Clinicorp, Inc., 887 F. Supp. 803, 803 (W.D. Pa. 1995). An injunction is not issued “simply to eliminate the possibility of a remote future injury.” Acierno, 40 F.3d at 665.

Furthermore, where the preliminary injunction seeks resolution of one of the ultimate issues presented in the Complaint, a preliminary injunction is improper:

Plaintiff's request for immediate relief in his motion for preliminary injunction necessarily seeks resolution of one of the ultimate issues presented in [the] Complaint[.] Plaintiff cannot demonstrate that he will suffer irreparable harm if he is not granted a preliminary injunction, because the ultimate issue presented will be decided either by this Court, upon consideration of Defendants' motion to dismiss, or at trial. As a result, Plaintiff's motion for preliminary injunction should be denied.

Messner v. Burner, 2009 WL 1406986, at *5 (W.D. Pa. 2009).

The Third Circuit has refused to relax this standard even in cases involving First Amendment claims. Conchatta, Inc. v. Evanko, 83 F. App'x 437, 442 (3d Cir. 2003). The assertion of First Amendment rights does not automatically require a finding of irreparable injury. Hohe v. Casey, 868 F.2d 69, 72–73 (3d Cir. 1989). Constitutional harm is not necessarily synonymous with the irreparable harm necessary for issuance of a preliminary injunction. Id. at 73. A plaintiff must show “real or immediate” danger to their rights “in the near future.” Anderson v. Davila, 125 F.3d 148, 164 (3d Cir. 1997).

Finally, in order to demonstrate irreparable harm the plaintiff must demonstrate potential harm which cannot be redressed by a legal or an equitable remedy following a trial. The preliminary injunction must be the only way of protecting the plaintiff from harm. Instant Air Freight Co. v. C.F. Air Freight, Inc., 882 F.2d 797, 801 (3d Cir. 1989). In the absence of a showing of bad faith enforcement or other extraordinary circumstances constituting irreparable harm to plaintiffs if enforcement is not enjoined, a preliminary injunction is inappropriate. See Woodruff v. W. Va. Bd. of Regents, 328 F. Supp. 1023, 1029 (S.D.W. Va. 1971). See also Younger v. Harris, 401 U.S. 37, 52–54 (1971) (holding that possible unconstitutionality of a

statute does not necessarily justify injunction against good-faith attempts to enforce it absent any showing of bad faith, harassment, or any other unusual circumstance requiring equitable relief).

Plaintiffs' filings fail to establish irreparable harm. They assert that they have refrained from marketing, selling, offering, describing, or educating others about EEKs in Pennsylvania out of fear of reprisal. See [ECF 2] at 37. Their contention is belied by the fact that their website is still active and accessible in Pennsylvania, despite the cease-and-desist notification. However, since Leda Health has never sold an EEK directly to an individual in Pennsylvania or New York, See Decl. of Madison Campbell [ECF 2-1] at ¶13, a denial of their injunction would maintain the status quo, and in no way result in irreparable harm to the company.

Furthermore, Plaintiffs have an adequate forum within which to challenge the Attorney General's enforcement action—the Allegheny County Court of Common Pleas. There, Plaintiffs could put forth their First Amendment arguments as affirmative defenses to the consumer protection suit against them. Rather than take the path laid out for them by the state courts, Plaintiffs instead mounted a First Amendment attack on the Attorney General's ability to enforce Pennsylvania's Consumer Protection Law—an attack that goes to the heart of one of the Office's core function as chief law enforcement officer for the Commonwealth. Specifically, its duty to protect Pennsylvanians from companies like Plaintiffs' that engage in unfair and deceptive business practices. Plaintiffs' Motion invites the federal courts to usurp the Attorney General's authority to enforce Pennsylvania's consumer protection laws—despite the General Assembly's clear intent to the contrary. See 73 P.S. § 201-4. This Court should refuse such a radical and unprecedented invitation by denying Plaintiffs' Motion for Preliminary Injunction.

D. Harm to Nonmoving Party

The third step in the analysis requires that the Plaintiff show that granting preliminary relief will not result in even greater harm to the nonmoving party. Kershner v. Mazurkiewicz, 670 F.2d 440, 443 (3d Cir. 1982). If the preliminary injunction were granted, the Court would frustrate the Pennsylvania Office of Attorney General's ability to enforce the consumer protection laws.

The Court must also consider the potential harm to third parties. See, e.g., Oburn v. Shapp, 521 F.2d 142, 152 (3d Cir. 1975). Specifically, the Court should place significant weight on the damage such kits would do to survivors of sexual assault if Plaintiffs' deceptive marketing tactics are allowed to continue unabated.

Plaintiffs market their EEKs to sexual assault survivors specifically. Analysis here only begins to scratch the surface of the potential issues that arise with self-collection of evidence following a sexual assault. Plaintiffs heavily imply that their EEKs provide substantially similar results as a sexual assault forensic exam performed by a healthcare facility in accordance with the Pennsylvania Department of Health's guidelines.

While a full recitation of all of the issues inherent in self-administered sexual assault examination is beyond the scope of this Response, they tend to fall within several discrete categories: (1) contamination of evidence collected; (2) an inadequate chain of custody; (3) creation of discoverable material through use of Plaintiffs' purported mobile app, which includes the ability to upload photos and videos; (4) potential novelty under Frye; (5) dubious admissibility; and (5) even assuming admissibility, trial issues including cross-examination by opposing party in a civil or criminal proceeding.

Plaintiffs purport to place the entirety of the burden of evidence collection on the sexual assault survivor themselves, failing to adequately warn them of the plethora of legal minefields

they are unknowingly setting for themselves. Given the short time period in which a person has to preserve evidence following a sexual assault, use of Plaintiffs' product has the potential to cause irreversible damages to a person's attempt to receive justice following an assault. They likely will not realize the damage done until it is too late.

Given the harm inherent in marketing and offering of EEKs to the public, the Court should deny the preliminary injunction.

E. Public Interest

Finally, assessment of the broader public interest also weighs against granting Plaintiffs' motion for preliminary injunction. In exercising their discretion, courts should pay particular regard for the public consequences in employing the extraordinary remedy of injunction.

Weinberger v. Romero-Barcelo, 456 U.S. 305, 312 (1982).

The Attorney General's enforcement action against Leda Health takes place within the context of nationwide concern over Plaintiffs' deceptive marketing tactics. Plaintiffs' product and advertising have drawn the ire of the Attorneys General of several states, including Michigan (Exhibit A), North Carolina (Exhibit B), Virginia (Exhibit C), New York (Exhibit D), Delaware (Exhibit E), Hawaii (Exhibit F), Florida (Exhibit G), and Connecticut (Exhibit H).

Attorneys general have expressed significant concern regarding Plaintiffs' marketing tactics, believing them to be in violation of their respective consumer protection laws. These states have either sent similar cease-and-desist letters to Leda Health, advising them that continued marketing in their states may result in legal action, or issued public warnings of Plaintiffs' deceptive business practices. Specifically, Pennsylvania, North Carolina, Michigan, New York, Florida, Hawaii, and Delaware have criticized Leda Health for failing to advise consumers that forensic exams—exams more thorough than the collection kits that Leda Health

advertises to the public at cost—are freely available to sexual assault survivors in those states. States have expressed other concerns, such as Plaintiffs’ inability to account for chain-of-custody issues (Virginia, Exhibit C) and their marketing’s overall impression that the evidence collected will be usable in court (New York, Exhibit D). Maryland and Washington have banned self-administered sexual assault kits outright. 2023 WA HB 1564 (Washington); Md. Code Ann., Com. Law § 14-4602 (West) (Maryland). The concerns expressed by elected attorneys general and state legislatures should not be taken lightly, and the Court should act with deference to their judgment, particularly at such an early stage of the litigation without the benefit of discovery.

Granting the preliminary injunction Plaintiffs seek would have nationwide consequences. Such relief would call into constitutional question the aforementioned laws passed in Washington and Maryland banning the kits at issue here. See HB 1564 (prohibiting the sale, offer, or provision of an “over-the-counter, at-home, or self-collected” sexual assault kit); *and* Md. Code Ann., Com. Law § 14-4602 (West) (“a person may not sell, offer for sale, or distribute a self-administered sexual assault evidence kit”). Plaintiffs are asking that the Court issue a ruling of multijurisdictional import. The Court should refuse Plaintiff’s invitation to “leapfrog” careful analysis and “just resolve the case” in their favor through a preliminary injunction. Del. State Sportsmen’s Ass’n, Inc. v. Del. Dep’t of Homeland Security, 2024 WL 3406290, at *1 (3d Cir. 2024). This would fly in the face of the *sole* purpose of a preliminary injunction—maintaining the status quo. Id. at *4. Prevailing case law, along with the facts borne out of the pleadings, mandate denial of Plaintiffs’ Motion.

V. CONCLUSION

WHEREFORE, Defendant, Pennsylvania Attorney General Michelle Henry, respectfully requests that this Honorable Court deny Plaintiffs’ request for a preliminary injunction.

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

| | | |
|------------------------------------|---|-------------------------------|
| LEDA HEALTH CORPORATION <i>and</i> | : | |
| MADISON CAMPBELL | : | |
| Plaintiffs | : | |
| | : | No. 2:24-CV-00879 |
| v. | : | |
| | : | Judge Bissoon |
| MICHELLE HENRY <i>and</i> LETITIA | : | |
| JAMES, | : | Electronically Filed Document |
| Defendants | : | |

CERTIFICATE OF SERVICE

I, Jorden P. Colalella, Deputy Attorney General for the Commonwealth of Pennsylvania, Office of Attorney General, hereby certify that on July 31, 2024, I caused to be served a true and correct copy of the foregoing document titled *Defendant's Brief In Opposition To Plaintiffs' Preliminary Injunction Motion* to the following:

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